Winter 2008

NORTH DAKOTA DEPARTMENT of HEALTH

Division of Health Facilities

DIALYSIS DIALOGUE

Welcome to this edition of ***Dialysis Dialogue***, a newsletter published by the North Dakota Department of Health, Division of Health Facilities. ***Dialysis Dialogue*** is designed to help dialysis departments stay up-to-date on various issues. Please share with your dialysis staff.

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Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota ESRD program from Oct. 1, 2005, to Sept. 30, 2007.

V265

The facility must be maintained and equipped to provide a functional, sanitary and comfortable environment.

V264

This requirement pertains to guidelines from the Association for the Advancement of Medical Instrumentation, regarding chemical contaminants and monitoring the water treatment system.

V143

The facility is responsible for promoting personnel practices that are consistent with procedures for sound patient care.

V266

This regulation states the facility must have written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items that conform to requirements for reuse.

V240

This regulation pertains to following the physician's orders; i.e. correct dialysate bath, flow rates, medications, etc.

V284

The facility must train patients to handle medical and non-medical emergencies. Patients must be fully informed regarding what to do, where to go and who to contact if a medical or non-medical emergency occurs.

Take a close look at your practices and identify if your facility is deficient in any of these areas. If so, take the appropriate actions necessary to correct these areas prior to your next survey. If you have questions about the deficiencies or the requirements, please contact the North Dakota Department of Health, Division of Health Facilities at 701.328.2352.

Delay in Release of New ESRD Regulations

The Centers for Medicare & Medicaid Services (CMS) has announced a delay in the release of the Conditions of Coverage for dialysis facilities by a year due to the high volume and complexity of comments from the renal community and other federal agencies on the draft released three years ago. The agency had until Feb. 4, 2008, to publish the Conditions of Coverage, based on regulations requiring the release of final rules no later than three years from the release of a draft regulation (Feb. 4, 2005). But the Social Security Act allows the Secretary of the Department of Health and Human Services to grant a delay due to exceptional circumstances. CMS said the extension on the final rule would not mean a re-start of the regulation development process. The renal community will not have the additional opportunity to comment formally on the rule.

Baxter Healthcare Recalls Heparin Sodium 1000 units/ml Multi-dose Vials (RX80360)

Baxter Healthcare is performing a voluntary recall of the below listed lots of Heparin Sodium 1000 units/ml for injection as a precaution due to an increase in reports of adverse patient reactions, including abdominal pain, decreased blood pressure, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, hypotension, lacrimation, increased loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, paresthesia (oral), pharyngeal edema, restlessness, vomiting/retching, stomach discomfort, tachycardia, thirst, trismus and unresponsiveness to stimuli.

NDC	LOT	DESCRIPTION	EXPIRATION DATE
00641-2440-45	107054	Heparin 1000 units/ml 10mL vial	10/2009
00641-2440-45	107054	Heparin 1000 units/ml 10mL vial	11/2009
00641-2450-45	047056	Heparin 1000 units/ml 30mL vial	10/2008
00641-2440-45	097081	Heparin 1000 units/ml 30mL vial	09/2009
00641-2440-45	107024	Heparin 1000 units/ml 30mL vial	10/2009
00641-2450-45	107064	Heparin 1000 units/ml 30mL vial	10/2009
00641-2440-45	107066	Heparin 1000 units/ml 30mL vial	10/2009
00641-2440-45	107074	Heparin 1000 units/ml 30mL vial	10/2009
00641-2450-45	107111	Heparin 1000 units/ml 30mL vial	10/2009

Please examine your inventory to determine if you have any affected product. If so, remove the affected product from your inventory and contact Baxter Healthcare Center for Service toll free at 888.229.0001 to arrange for return and credit.

Baxter is in the process of an in-depth investigation to determine the root cause of the reported reactions and has notified the FDA of the recall. If you have any technical or clinical questions, please contact Baxter Healthcare Corporation Product Information Center at 800.933.0303.

On Feb. 11, 2008, Baxter International announced the temporary cessation of production of the Heparin multi-dose vials after reports of more than 350 adverse reactions to the drug, including four deaths. Most of the reactions have taken place at hemodialysis centers, almost exclusively involving patients receiving a bolus dose.

Questions and Answers (Q&A)

CMS provides specialized technical ESRD training courses (basic, accelerated and advanced) for state surveyors, as well as an annual ESRD update. During these training courses, surveyors from across the country ask CMS staff questions regarding the ESRD survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. Readers are welcome to submit questions to bweidner@nd.gov.

Q: ***Do bicarbonate spills that dry and are left in the mixing area provide a risk for bacterial growth, or only if it is "wet"?***

A: Consider:

- Would expect the mix area be kept clean and residue be removed – it will destroy surfaces over time, which results in surfaces that can't be cleaned. Dry residue would not be a risk for bacterial growth. V256 requires building and equipment be maintained to ensure patient/staff safety.

Q: ***If the patient brings home records in, can the nurse rewrite the records in a summary and discard the originals?***

A: No. The patient-generated records must be incorporated into the permanent record.

Q: ***Should there be a contract or agreement with labs where water cultures are done to spell out how to handle the specimens after collection and how to transport them?***

A: Yes. There is a requirement at V156 for contracts with outside resources to specify responsibilities.

Q: ***Should facilities perform manual off-line conductivity testing if their machines have internal sensors that are more sensitive?***

A: Consider:

- AAMI RD 52 recommends no separate testing for the new machines. We need to continue to follow manufacturer's guidance, which generally requires separate testing.

Q: ***Is it okay for a facility to use a bag of normal saline labeled in part, single dose, to fill multiple syringes for multiple patients?***

A: The Centers for Disease Control and Prevention does not directly address this issue in writing: Observe care. Observe to see whether bag is accessed using appropriate aseptic techniques. Large-volume parentals do not contain preservatives. Look at how long the saline bag is used after being opened.

If your facility would like to receive *Dialysis Dialogue* electronically, please send your e-mail address to bweidner@nd.gov

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